



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

HFI-35 12/19/97
718

Food and Drug Administration
One Montvale Avenue
Stoneham, MA 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

December 9, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NWE-07-98W

Chester Baran, M.D.
Radiologist
Nantucket Cottage Hospital
57 Prospect Street
Nantucket, MA 02554

Dear Dr. Baran:

Your facility was inspected on October 28, 1997 by a representative of the Commonwealth of Massachusetts, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

[REDACTED] an interpreting physician, is unqualified to interpret mammograms due to the lack of being board certified by any of the approved boards or having two months full-time training in the interpretation of mammograms.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliances are:

██████████ did not meet the initial training requirement of having 40 hours of continuing medical education in mammography.

██████████ did not meet the initial experience requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiating permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

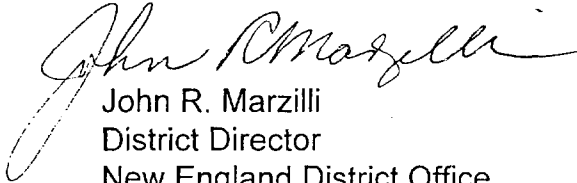
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to Michael J. Leal, MQSA Auditor, Food and Drug Administration, 120 Front Street, Suite 680, Worcester, MA 01608. Also send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Mr. Leal at 508-793-0422.

Sincerely yours,



John R. Marzilli
District Director
New England District Office

cc: Commonwealth of Massachusetts
Radiation Control Program
Department of Public Health
305 South Street
Jamaica Plain, MA 02130